

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JENNIFER MAITRE, Individually,
and as Mother, Guardian and Next Friend of
CHRISTIAN FRANCIS MAITRE,
A Minor,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Civil Action No. 05-CV-19442 (JLT)

**DEFENDANT ELI LILLY AND COMPANY’S MEMORANDUM OF POINTS AND
AUTHORITIES IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT**

Defendant Eli Lilly and Company (“Lilly”) moves for summary judgment under Fed. R. Civ. P. 56 on all claims asserted by minor plaintiff (“CM”). CM alleges that his claimed injuries are the result of his mother’s (“Mrs. Maitre”) *in utero* exposure to Lilly’s diethylstilbestrol.¹ Massachusetts law, however, has not recognized, and in all likelihood, will not recognize “third generation” product liability suits sounding in tort.² Massachusetts courts have rejected “pre-conception torts” -- where the plaintiff claims injury from tortious action to the infant’s mother occurring before his or her conception -- because of an inability to sensibly analyze the concepts of duty, foreseeability, and causation in this context. These concerns are heightened in the context of third generation claims where a plaintiff’s claimed injury is one step further removed

¹ CM’s mother, Jennifer Maitre, was originally a plaintiff in this litigation. On June 15, 2006, Jennifer Maitre filed a stipulation of dismissal with respect to her claims only. *See* Docket Entry No. 28.

² “Third generation” in the DES context refers to the alleged causal chain between a mother who ingested DES (first generation), a daughter who was exposed to DES *in utero* as a result of said ingestion (second generation), and a child born many years later to the DES-exposed daughter (third generation). Third generation DES plaintiffs were never exposed to the drug.

from the tortious action -- sale of a pharmaceutical drug to the claimant's grandmother -- that allegedly caused it. Further, every appellate jurisdiction that has squarely faced third generation DES claims have rejected them, based on the same policy considerations cited by Massachusetts courts. CM's third generation claims are simply not cognizable in Massachusetts.

**DEFENDANT ELI LILLY AND COMPANY'S STATEMENT OF MATERIAL FACTS
AS TO WHICH THERE IS NO GENUINE ISSUE³**

1. In the Complaint, CM, through her mother, Jennifer Maitre, alleges negligence and strict liability. Complaint ¶¶ 22 - 31 (copy attached as Exhibit 1 to Affidavit of Brian L. Henninger ("Henninger Aff.")). CM seeks compensatory and punitive damages. *Id.* at ¶ 32.

2. CM's grandmother, Mary Susan Bane ("Ms. Bane"), became pregnant with Mrs. Maitre in February 1963 while she was living in Needham, Massachusetts and allegedly ingested DES during that pregnancy. *See id.* at ¶ 4 (Henninger Aff.) (alleging exposure in Massachusetts); Mrs. Maitre's Answers to Lilly's First Set of Interrogatories ("Interrog.") at Nos. 1, 12 (copy attached as Exhibit 2 to Henninger Aff.) (stating that the approximate date and place of Mrs. Maitre's conception). Mrs. Maitre was born in November 1963 in Boston, Massachusetts. *Id.* at No. 1.

3. Mrs. Maitre became pregnant with CM in November 1998, more than thirty-five years after his mother's alleged exposure to diethylstilbestrol. *Id.* at No. 15(b). CM was born at 28 weeks gestation in June 1999. *Id.*

4. CM has never been exposed to diethylstilbestrol. Complaint at ¶ 23 (Henninger Aff., Ex. 1).

³ Lilly accepts these facts as undisputed for purposes of this summary judgment motion only and reserves the right to contest any of these facts at trial.

ARGUMENT

I. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate “if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56(c); *Carroll v. Xerox Corp.*, 294 F.3d 231, 236-37 (1st Cir. 2002). Once the moving party has pointed to the absence of adequate evidence supporting the nonmoving party's case, the nonmoving party must come forward with facts that show a genuine issue for trial. *Carroll*, 294 F.3d at 236. Neither “conclusory allegations [nor] improbable inferences” are sufficient to defeat summary judgment. Rather, to withstand a properly supported motion for summary judgment, the opposing party must present “enough competent evidence” to enable a factfinder to decide in its favor on the disputed claims. *Id.* at 236-37 (quoting *Goldman v. First Nat'l Bank of Boston*, 985 F.2d 1113, 1116 (1st Cir. 1993)) (citations omitted).

II. LILLY IS ENTITLED TO SUMMARY JUDGMENT BECAUSE MASSACHUSETTS DOES NOT RECOGNIZE THIRD GENERATION CLAIMS.

CM has not alleged a cognizable cause of action in Massachusetts. A thorough review of Massachusetts case law reveals that no court in the Commonwealth has ever recognized “third generation” claims. Furthermore, it is highly unlikely that Massachusetts *would* recognize a third generation DES cause of action. Massachusetts courts have considered the viability of preconception torts several times and rejected such causes of action. Moreover, every appellate jurisdiction that has squarely considered the viability of third generation DES claims has rejected them, based on the same policy considerations that Massachusetts has endorsed.

A. The Substantive Law of Massachusetts Governs Plaintiff's Claims.

Massachusetts substantive law governs this action because all of the operative events related to the prescription and use of diethylstilbestrol occurred there. *Boston Co. Real Estate Counsel v. Home Ins. Co.*, 887 F. Supp. 369, 372 (D. Mass. 1995) (holding that in Massachusetts, “the law of the jurisdiction with the ‘most significant relationship’ to the transaction governs the dispute”). Mrs. Maitre’s alleged exposure to DES took place in Massachusetts, where she was born, where her mother lived during her pregnancy, where her mother allegedly was prescribed DES and filled her prescription for DES, and where she currently resides. Interrog. Nos. 1, 2, 5, 6, 7 (Henninger Aff., Ex. 2). In addition, CM was born in Massachusetts and has resided there with his parents continuously since his birth. *See* Jennifer Maitre’s Responses to Lilly’s First Set of Interrogatories as Mother, Guardian, and Next Friend of CM (“CM Interrogs.”) No. 1 (copy attached as Exhibit 3 to Henninger Aff.). Further, all of CM’s injuries have been diagnosed and treated in Massachusetts. *Id.* at Nos. 5-6.

B. Third Generation Tort Suits Raise the Same Public Policy Concerns That Led Massachusetts to Reject Preconception Tort Suits.

Massachusetts courts have never recognized third generation tort claims in the DES context or any other. Further, Massachusetts appellate and federal courts have already considered “preconception” tort claims and rejected them. *See McNulty v. McDowell*, 613 N.E.2d 904 (Mass. 1993) (declining to recognize a cause of action for a child harmed by measles based on a doctor’s failure to administer a rubella test to the plaintiff’s mother before plaintiff was conceived); *Angelini v. OMD Corp.*, 575 N.E.2d 41, 43 (Mass. 1991) (rejecting loss of consortium claims for children conceived after parent was injured); *see also Lareau v. Page*, 840 F. Supp. 920, 930 (D. Mass. 1993) (*aff’d* by *Lareau v. Page*, 39 F.3d 384 (1st Cir. 1994) (rejecting a loss of consortium claim by a daughter who was conceived after her mother was

injured). Preconception tort claims involve only two generations (parent and child), two medical histories, and a short span of time between tortious action affecting a parent and resultant injury to a subsequently conceived child. Third generation torts involve three generations (grandmother, mother and minor plaintiff), three medical histories, and in this case, a thirty-five year gap between DES ingestion by the grandmother and alleged injury to the minor plaintiff. CM's third generation DES claim would constitute a more radical extension of liability than the "preconception tort" already rejected by Massachusetts in that it presents a more distant generation of plaintiffs, causation attenuated over more years and more generations, and the prospect of unlimited liability spanning generations beyond the reasonable ken of any manufacturer.

The remoteness of the alleged injury, the potential for unlimited litigation and the deterrent effect of third generation suits on new drug development are all factors that weigh against recognition of such suits in Massachusetts.

1. Remoteness of third generation claims

It is a fundamental precept of common-law negligence that a plaintiff must demonstrate, among other things, that the defendant owed a duty to the plaintiff, that injury to the plaintiff was reasonably foreseeable to the defendant, and that the defendant's alleged act was the proximate cause of the plaintiff's injury. *Primus v. Galgano*, 329 F.3d 236, 241 (1st Cir. 2003) (applying Massachusetts law) (*quoting Heinrich v. Sweet*, 308 F.3d 48, 62-63 (1st Cir. 2002)). In a third generation DES claim, the duty, foreseeability, and causation elements are almost impossible to satisfy, not least because the third generation plaintiffs were never exposed to the drug and did not exist at the time of the alleged wrong. Consequently, third generation allegations must rely on "the rippling effects of DES exposure." *Enright*, 570 N.E.2d at 203; *Grover*, 591 N.E.2d at 699.

“Rippling effects,” however, are not enough to impose liability. Recognizing the practical limits of foreseeability, the *Grover* court found it “difficult to imagine that a pharmaceutical company, during the 1940s to the 1960s, could have foreseen the effect that a drug would have not only on a patient's child, but also on that children's children.” *Grover*, 591 N.E.2d at 698 n.1. The court therefore held explicitly that a manufacturer's duty does not extend to the third generation: “Where a pharmaceutical company prescribes drugs to a woman, the company, under ordinary circumstances, does not have a duty to her daughter’s infant who will be conceived twenty-eight years later.” *Grover*, 591 N.E.2d at 700. The *Grover* case dealt with claims very comparable to those made here.

Massachusetts has also made clear that a defendant has no duty to protect against remote, unlikely, or unforeseeable occurrences. See *Lindberg v. Gilbert*, 190 N.E.2d 105, 106 (Mass. 1963) (“the defendant was not bound to guard against what was only remotely likely to occur”); *Glick v. Prince Italian Foods of Saugus, Inc.*, 514 N.E.2d 100, 102 (Mass. App. Ct. 1987) (“the court will not hold the defendant liable for all possible injury no matter how remote”); cf. *Vassallo v. Baxter Healthcare Corp.*, 696 N.E.2d 909, 923 (Mass. 1998) (abandoning the “hindsight approach” to implied warranty of merchantability suits, which charged product manufacturers with knowledge of all risks associated with a product regardless of the state of the art, in favor of an approach that charges manufacturers with risks that are foreseeable at the time of sale or could have been discovered with testing prior to marketing). The injuries alleged in third generation DES claims - where harm is physically, temporally and generationally removed from actual ingestion of the drug - are precisely the kind of remote or unlikely occurrences that Massachusetts courts have found, as a matter of policy, to be non-litigable.

The remoteness of third generation claims affects not only duty and foreseeability but also causation. The Ohio Supreme Court made lack of proximate cause a specific basis for rejecting third generation DES claims, holding that “[b]ecause of the remoteness in time and causation, [the plaintiff] does not have an independent cause of action.” *Grover*, 591 N.E.2d at 700.

Massachusetts has expressed similar concerns about remoteness saying, as example, that “as a matter of policy, it must be recognized that tort liability cannot be extended without limit.” *Feliciano v. Roseman Silver Co.*, 401 Mass. 141, 142 (1987) (refusing to extend loss of consortium claims to non-married couple). Massachusetts also, like most states, recognizes that claims based on events in the distant past raise troubling issues of lost evidence, unavailable witnesses, and confusion over the applicable state of the art. *See Klein v. Catalano*, 437 N.E.2d 514, 521, n.11 (Mass. 1982) (approving the policies underlying a legislative statute of repose). Given Massachusetts’s clear holdings on the limitation of liability for remote or unforeseeable claims, and given the numerous foreseeability problems associated with third generation DES claims, Massachusetts is likely to reject third generation DES liability on doctrinal grounds.

2. Extending liability beyond manageable bounds

In addition to being incompatible with traditional tort doctrine, third generation DES claims violate public policy by inviting the extension of tort liability beyond reasonable bounds. Recognition of third generation liability increases the number of potential litigants and greatly extends the amount of time during which suits may be brought. Because a third generation plaintiff “cannot be injured until the original patient's child bears children, the second injury will typically have occurred more than sixteen years after the ingestion of the drug.” *Grover*, 591 N.E.2d at 699. Furthermore, because allowing third generation claims opens the door for fourth, fifth, or successive generations - each usually 20 to 30 years apart - to bring claims based on an

increasingly remote ancestor's alleged exposure, the period of liability if third generation claims are recognized is potentially limitless. In their gate-keeping role, courts assessing DES-related claims have always drawn the line at the second generation, the last generation where direct exposure to the drug was possible. *See, e.g., Enright*, 570 N.E.2d at 203; *Grover*, 591 N.E.2d at 699.

Largely because of these policy concerns, Massachusetts has steadfastly refused to recognize preconception torts. In *Angelini*, 575 N.E.2d at 42, the plaintiff sued for loss of consortium resulting from injuries his father sustained in an automobile accident. The plaintiff was *in utero* at the time his father was injured. The Supreme Judicial Court held that the plaintiff could proceed on his claim, but only because he had been conceived *before the time of injury* and was later born alive. *Id.* at 46. The court explained:

A child conceived after the injury, and eventually born alive, may suffer the same loss of parental consortium as a child conceived before the injury and also born alive. It may be asked, therefore, why should the latter be allowed to recover for loss of consortium and not the former? The answer is that, after a parent is negligently injured by a defendant, he or she may continue having children for many years. *If no restriction is placed on the class of children who are eligible to recover for loss of parental consortium, a defendant may become liable for the loss of consortium several years, perhaps even decades, after the injury to the parent. As a matter of policy, however, it is important to limit the duration of liability.*

Id. at 43 (emphasis added). Two years later, in *Lareau*, a federal district court applying Massachusetts law barred a loss of consortium claim by a daughter who was conceived after her mother had discovered she had a brain injury, holding that “the *Angelini* decision necessarily bars actions by children conceived after the cause of action of the parent should have been known.” *See Lareau*, 840 F. Supp. at 930 (citing the same policy concern about placing limits on defendant liability); *McNulty v. McDowell*, 613 N.E.2d 904, 907 (Mass. 1993) (refusing to recognize a duty of care running from a physician to a child not yet conceived based on the mere

fact that a twenty-two year old patient is of child-bearing age in part because the physician cannot identify steps to limit liability).

Angelini, Lareau, and McNulty demonstrate that Massachusetts will not permit claims - particularly preconception tort claims - that could lead to liability without end. The logic of the *Angelini* opinion transfers naturally to the DES context: if no restriction is placed on the class of plaintiffs who can allege injury due to DES exposure two or more generations prior, a defendant may become liable decades after the initial injury allegedly occurred. Following its own case law and that of other jurisdictions, Massachusetts is likely to dictate that the duration of DES liability must be limited to the second generation. *See Angelini*, 575 N.E.2d at 43.

The Supreme Judicial Court recently employed analogous reasoning in barring minor plaintiffs from suing their own mothers for injuries negligently inflicted while they were *in utero*. *Remy v. MacDonald* involved a minor plaintiff who brought suit against her mother for chronic respiratory injuries stemming from an emergency caesarian section necessitated by her mother's negligent operation of an automobile. 801 N.E.2d 260, 262 (Mass. 2004). The Supreme Judicial Court imposed a blanket bar on such suits citing several doctrinal and policy concerns. Foremost among those concerns was the fact that "recognizing a pregnant woman's legal duty of care in negligence to her unborn child would present an almost unlimited number of circumstances that would likely give rise to litigations." *Remy*, 801 N.E.2d at 263. The same concern about boundless opportunities for litigation stemming from stale and fragmented facts that led the Supreme Judicial Court to reject liability in *Angelini* and *Remy* would lead it to reject third generation DES claims as well.

3. Deterring the manufacture of beneficial drugs

Recognizing third generation liability will also have detrimental effects on the research and development of new and useful drugs. As the *Enright* court explained, "public policy favors

the availability of prescription drugs even though most carry some risks [W]e are aware of the dangers of over-deterrence - the possibility that research will be discouraged or beneficial drugs withheld from the market. These dangers are magnified in this context, where we are asked to recognize a legal duty toward generations not yet conceived.” 570 N.E.2d at 204.

The *Enright* court’s concern about over-deterrence is not unique. Massachusetts has explicitly cabined potential liability in DES cases so as not to deter research and development. In *Payton v. Abbott Laboratories*, 437 N.E.2d 171 (Mass. 1982), the Supreme Judicial Court refused to impose market share liability on DES manufacturers, concluding that “[p]ublic policy favors the development and marketing of new and more efficacious drugs.... Imposition of such broad liability could have a deleterious effect on the development and marketing of new drugs, especially those marketed generically.” *Payton*, 437 N.E.2d at 189-90. To make the point clear, the court added, “[i]ndeed, if a cure for clear-cell adenocarcinoma lies in the development and manufacture of some new drug, imposing market share liability might prevent the marketing of a cure for the very cancer threatening the plaintiffs.” *Id.* at 190 n.18. Given its stated policy of declining to extend tort liability where it would detrimentally affect the research and development of beneficial drugs, Massachusetts is unlikely to deviate from current law and permit third generation claims that by *definition* extend tort liability beyond traditional bounds.

The chilling effect that unwarranted extensions of tort liability have on research and development of useful products has long been recognized. *See, e.g.,* P.W. Huber, *Liability: The Legal Revolution and Its Consequences* 155 (1988) (describing the loss of innovation in the pharmaceutical industry as a result of the growth of tort liability). As one court explained:

[T]he ultimate cost of product liability is not usually seen in the closing of existing factories, but rather in research and development *not* pursued, new technologies *not* developed, new products *not* introduced, new factories *not* built, and new jobs *not* created.

Blankenship v. General Motors Corp., 406 S.E.2d 781, 783 n.4 (W. Va. 1991) (citing E.P. McGuire, *The Impact of Product Liability*, Conference Board Report No. 908, at p. 28, Table 30 (1988)) (emphasis in original). Sharing these concerns, courts around the country have routinely refused to extend product liability beyond traditional limits.⁴

Massachusetts has not recognized third generation torts. Recognition of such claims would run counter to traditional tort doctrines on duty, foreseeability, and causation that have long been embraced in Massachusetts and elsewhere. No other appellate jurisdiction has recognized third generation DES claims. For all these reasons, Lilly is entitled to summary judgment as to the third generation claims of CM.

C. Every Appellate Jurisdiction That Has Squarely Addressed Third Generation DES Claims Has Denied A Cause of Action.

There is no basis to believe Massachusetts would depart from the overwhelming rejection of third generation DES claims by other appellate courts. To date, five appellate jurisdictions have squarely addressed third generation claims in the DES context,⁵ and all five have refused to let the claims go forward. *See Wood v. Eli Lilly & Co.*, 38 F.3d 510, 513-14 (10th Cir. 1994) (affirming grant of summary judgment to manufacturers and distinguishing third generation from second generation DES cases because “there is less certainty that a known ingestion of DES presents a consistent singular risk of a digestive tract injury to the grandchild of a person

⁴ *See, e.g., Browning-Ferris Indus. of Vermont, Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 282 (1989) (O'Connor, J., concurring and dissenting) (noting that the threat of punitive damage awards “has a detrimental effect on the research and development of new products”); *Conafay v. Wyeth Labs.*, 1985 U.S. Dist. LEXIS 21618 at *8-9 (D.D.C. 1985) (recognizing that imposing strict liability in cases involving drugs “would chill if not smother the research, development, production and marketing of new prescription or experimental drugs necessary to alleviate or cure the ills to which all persons are subject”); *Pollard v. Ashby*, 793 S.W.2d 394, 399 (Mo. Ct. App. 1989) (determining that “withholding a drug from the market ... until scientific skill and knowledge advanced so that additional dangerous side effects might be revealed ... would not serve the public interest”).

⁵ In addition, two federal district courts have considered third generation DES claims and rejected them. *See Sorrells v. Eli Lilly & Co.*, 737 F. Supp. 678 (D.D.C. 1990) (construing Maryland law to impose no duty to the unborn grandchild of a woman who ingested DES); *Fotsch v. Eli Lilly & Co.*, 995 U.S. Dist. LEXIS 5227, at *3, *10 (N.D. Ill. 1995) (applying *Sparapany*, and refusing to entertain the third generation DES claims of minor plaintiffs).

ingesting the drug); *Sparapany v. Rexall Corp.*, 618 N.E.2d 1098 (Ill. Ct. App. 1993) (concluding that Illinois law precludes the imposition of a legal duty to third generation claimants if the alleged conduct occurred prior to 1977);⁶ *Grover v. Eli Lilly & Co.*, 591 N.E.2d 696 (Ohio 1992) (holding, on certification from the federal district court, that there is no duty to a third generation plaintiff); *Enright v. Eli Lilly & Co.*, 570 N.E.2d 198 (N.Y. 1991) (denying a third generation claim premised on strict liability⁷); *see also Loerch v. Eli Lilly & Co.*, 445 N.W.2d 560 (Minn. 1989) (summarily affirming a trial court's rejection of third generation claims). These courts were concerned with the doctrinal and public policy consequences of extending potential liability beyond the boundaries of traditional tort law. In particular, *Enright* and *Grover*, the two cases to most fully address third generation DES claims, expressed deep concern about the potential for unlimited liability of DES pharmaceutical manufacturers, and voiced the need to “confine liability within manageable limits.” *Enright*, 570 N.E.2d at 203.

Some jurisdictions have allowed preconception tort claims involving second generation plaintiffs, clear causation, and a limited scope of liability. *See e.g. Renslow v. Mennonite Hospital*, 367 N.E.2d 1250, 1255 (Ill. 1977) (allowing preconception tort suit based on Rh-sensitization because it was “clearly distinguishable” from suits where “successive generations of plaintiffs complain against a single defendant for harm caused by genetic damage done [to] an ancestor...”); *Monusko v. Postle*, 437 N.W.2d 367, 370 (Mich. Ct. App. 1989) (allowing preconception tort suit based on rubella testing, emphasizing “the direct connection between the

⁶ Two decisions from Illinois, reported *prior* to *Sparapany*, failed to substantively address the presence of third generation plaintiffs at the earliest stages of litigation, thus allowing the suits to move forward. *See Bowe v. Abbott Labs.*, 608 N.E.2d 223 (Ill. Ct. App. 1992) (allowing plaintiffs to amend complaint to allege alternative liability rather than market share liability without addressing the presence of a third generation plaintiff in the suit); *McMahon v. Eli Lilly & Co.*, 774 F.2d 830 (7th Cir. 1985) (reversing grant of summary judgment to defendant on product identification and unforeseeability grounds without addressing presence of third generation plaintiff).

⁷ The lower court in *Enright* had previously refused to allow third generation claims premised on negligence and breach of warranty, and appellants did not challenge this decision on appeal. *See Enright*, 570 N.E.2d at 200.

[rubella] test and immunization procedure and the harm in this case”). These decisions are extremely poor predictors of how Massachusetts would handle third generation DES claims, which involve a more distant generation of plaintiffs, attenuated causation, and potentially unlimited liability.

CONCLUSION

Lilly is entitled to summary judgment on all claims asserted by CM because Massachusetts law simply does not recognize third generation torts.

REQUEST FOR ORAL ARGUMENT

Pursuant to LR 7.1(D), Lilly requests a hearing on its Motion for Summary Judgment.

Respectfully submitted,

ELI LILLY AND COMPANY
by its attorneys

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Dated: June 15, 2006

LR 7.1(A)(2) CONFERRAL CERTIFICATION

I certify that counsel for Lilly contacted Plaintiffs’ counsel on June 15, 2006 to attempt in good faith to resolve or narrow the issues addressed in this Motion. The parties were unable to resolve or narrow said issues.

/s/ Brian L. Henninger